UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff and Respondent,

v.

W. SCOTT HARKONEN,

Defendant and Petitioner.

Case No. 08-cr-00164-RS-1

ORDER DENYING PETITION FOR THE WRIT OF ERROR CORAM NOBIS

I. INTRODUCTION

Petitioner and defendant W. Scott Harkonen moves this Court to set aside his conviction under the federal wire fraud statute, 18 U.S.C. § 1343, pursuant to the common law writ of error coram nobis, on the grounds that he received ineffective assistance of counsel within the meaning of *Strickland v. Washington*, 466 U.S. 668 (1984). While, in the clarity of hindsight, different decisions on the part of Harkonen's trial attorneys may well have won him a more favorable result, their exercise of judgment was not so beyond the pale of reasonable conduct as to warrant the finding of ineffective assistance necessary to grant Harkonen's request for relief. Harkonen, moreover, does not show valid reasons for failing to raise his claim of ineffective assistance at an earlier juncture. His petition must therefore be denied.

II. BACKGROUND

Harkonen, a doctor and CEO of the biotechnology company InterMune, Inc., on April 13, 2011 received a sentence of three years of probation following a jury verdict finding him guilty as

to one count of wire fraud under 18 U.S.C. § 1343, premised on the making of false or misleading statements with the intent to defraud or mislead. Specifically, Harkonen was found to have approved a press release announcing the preliminary results of a clinical study, the GIPF-001 trial, for the drug Actimmune in treating fatal lung disease (idiopathic pulmonary fibrosis, or "IPF"). The press release, as charged, contained false and misleading information regarding Actimmune and falsely portrayed the results of the trial as demonstrating that the drug helped patients live longer. The particular statements at issue in the press release were its headline, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," and the subheading "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." The jury furthermore found that these statements were made for the purpose of inducing doctors to prescribe, and patients to take, Actimmune for IPF.

An allegation regarding the significance of data collected during a medical experiment comprises a scientific opinion. Because federal fraud statutes forbid prosecution concerning scientific opinions about which reasonable minds may differ, the government bore the burden in this case to prove that the opinions expressed in the press release's caption were not, and could not have been, held by reasonable experts in the fields of biostatistics or pulmonology. The prosecution thus advanced the theory that no reasonable scientist could have, in good faith, reported the trial to be anything but an abject failure because its results did not meet certain statistical principles it argued were immutable.

The GIPF-001 study was a randomized, double-blind, placebo-controlled experiment to test Actimmune as a treatment for IPF. It primary endpoint, or target outcome, was "progression-free survival," with progression measured by decreased lung function, oxygen deficiency in the lungs, or death. Pet. for Writ of Error Coram Nobis, p. 7. At its outset, the study also identified nine secondary endpoints, the seventh being survival time in the two years from the study's commencement to its cut-off date.

In clinical trials, a p-value is a number between one and zero which represents the probability that the results establish a cause-and-effect relationship, rather than a random effect,

between the drug and a positive health benefit. Because a p-value indicates the degree to which the tested drug does not explain observed benefits, the smaller the p-value, the larger a study's significance. Study data referred to as "statistically significant" thus has a p-value lower than the study's predetermined p-value threshold for significance. In general, the statistical integrity of results concerning secondary endpoints hinge on the primary endpoint achieving statistical significance. Clinical study protocols often set out, prior to commencing research, threshold p-values, primary and secondary endpoints, and planned tests, in order to promote objective analysis not dictated by the motive to demonstrate success.

Here, the GIPF-001 team chose a p-value of 0.05 as its cutoff for statistical significance of its various endpoints. GIPF-001did not yield statistically significant results on its primary endpoint; the p-value for progression-free survival time was 0.52. Nor did the analysis for any of the secondary endpoints yield a p-value lower than 0.05. While the plan for GIPF-001 did not include at its outset an intent to perform such an analysis, a post-hoc tabulation of data from a subgroup of patients with mild to moderate IPF showed a survival benefit with a p-value of 0.004. The survival p-value for the overall patient group was, by contrast, 0.084. It was on the basis of this data that the press release reported a trend in survival data that appeared to demonstrate a benefit.

In making its case, the prosecution therefore stressed testimony from its experts touting the view that study results without sufficiently low p-values are inherently unreliable and meaningless. The government also produced evidence suggesting Harkonen misrepresented the GIPF-001 trial's results before the Food and Drug Administration ("FDA") in the face of doubts expressed to him by other scientists involved in the study, and kept plans to publish the press release secret from his colleagues while purporting to have full support at InterMune for the conclusions it contained.

In March 2008, Harkonen was indicted by a federal grand jury on two counts: (1) wire fraud under 18 U.S.C. § 1343, and (2) misbranding, under 21 U.S.C. §§ 331(k), 333(a)(2), and 352(a). From the case's inception up until sentencing, Harkonen received representation from a

trial team spearheaded by Marcus Topel and including Lyn Agre and William Goodman, all of the firm Kasowitz, Benson, Torres & Friedman, as well as Ann Moorman, now a superior court judge. Harkonen also hired Ron Winchell as independent counsel to advise him privately on all matters related to the case, and engaged Paul Kalb and Coleen Klasmeier, attorneys at Sidley Austin LLP, to assist with locating potential defense experts and certain pre-trial motions.

In its pretrial disclosures, the government indicated its intent, as to issues of biostatistics and study interpretation, to rely on testimony from Michael Crager, an InterMune biostatician, and Thomas Fleming, a professor of biostatistics who chaired a group of scientists appointed to oversee the GIPF-001 trial to safeguard patient interests (the Data Monitoring Committee, or "DMC"). The Topel team, in response, disclosed six experts: Lawrence Mayer and Patrick Hannon (both biostatistics experts), Roger Mayfield and Joseph Zibrak (both as clinical experts), and David Katz and Kathryn Zunich (other physicians identified as experts on drug regulation and advertising). The trial judge denied the government's motion in limine to exclude these defense experts.

Throughout its case in chief, the government stressed testimony from Fleming and Crager who offered that, in the world of biostatistical analysis, a 0.05 p-value threshold is "somewhat of a magic number"; that the only meaningful p-value from a study is the one for its primary endpoint; and that data from post-hoc subgroup analyses cannot be reported upon accurately without information about the rest of the sampling context. *See* Pet. for Writ of Error Coram Nobis, p. 72. That the primary endpoint p-value for GIPF-001 was 0.52 rendered all other reported outcomes from the study, in their opinions, not only statistically insignificant, but devoid of any value at all.

As the government approached the close of evidence, it again moved to exclude defense testimony on statistical theories, arguing that its witnesses had laid the necessary groundwork for the jury to understand the relevant statistical methodology, and that no defense expert evidence on that score was warranted. Harkonen, countering that such exclusion of its experts would infringe his constitutional right of defense, again prevailed before the trial judge. Subsequent proceedings took place in which defense counsel discussed with the Court the intended scope of expert witness

examination. Then, after calling a small number of percipient witnesses, the defense rested its case without calling any experts. Harkonen's current motion focuses on this decision, which left "undisputed," in the words of the trial judge, the government expert's testimony that the GIPF-001 trial was a failure.

The nature of Harkonen's allegations implicate several specific details of his attorneys' efforts. The defense team had scoured the country for over a year for potential defense biostatistics experts prepared to testify that the press release was accurate against the word of Dr. Fleming, whom the defense knew was likely to serve as a cornerstone witness in the government's case. Numerous interviews yielded just two—Mayer and Hannon. Members of the trial team met multiple times with both experts, focusing in particular on confirming Mayer's position on the press release and preparing him to testify. At the case's outset, Mayer appeared to be a particularly important witness for the defense because his credentials rivaled those of Fleming, and he was prepared to challenge the prosecution on the fundamental principles of biostatistical analysis.

The search for pulmonologists proved similarly challenging; many members of the DMC were averse to Harkonen's position, and one joined the government's panel of witnesses alongside Fleming. Over two hundred calls to a list of Actimmune-prescribing physicians garnered just two responses, from Zibrak and Maxfield. A particular strategic challenge confronted the defense regarding pulmonology testimony. Having successfully won the exclusion from the trial of evidence of a study subsequent to the GIPF-001 trial supportive of press release falsity (the "GIPF-007 trial"), the defense risked opening the door to the GIPF-007 results on cross examination of any pulmonology witnesses regarding current knowledge as to Actimmune's efficacy and its ongoing use.

Still unsatisfied with the few experts identified through their extensive searches, the Topel team cast a broader net among physicians with drug regulation and advertising expertise willing to testify on Harknonen's behalf, which led to Zunich and Katz. Harkonen's attorneys also twice reviewed, but decided against including, a DVD compilation of various scientists' impressions of

the GIPF-001 trial and of the efficacy of Actimmune shared at various scientific conferences and meetings. The reactions reflected on the tape were either mixed or irrelevant, with physicians in some instances indicating disagreement with the trial results or purported benefits of Actimmune.

Topel stated at the commencement of trial that he intended to call expert witnesses to speak to the GIPF-001 study's statistical significance and the benefits of Actimmune. Over the course of the prosecution's case, the defense established a number of points in Harknonen's favor on cross examination. For instance, Crager, who had filed a patent application for Actimmune, had attested in the application to the existence of statistically significant evidence of the drug's positive effect on patients' likelihood of survival. He furthermore did not report any negative impressions of the draft press release to Fleming, and had created a slide demonstrating a statistically significant outcome of GIPF-001, without any qualifying statements. Other government witnesses admitted they had known of the forthcoming press release and neither harbored nor expressed concerns as to its accuracy; had heard DMC members emphasize the significance of GIPF-001's demonstrated survival benefits to IPF patients; and had themselves extolled its successes.

In defense counsel's judgment at the time, the headway made during the government's case ultimately obviated the need for defense experts, especially in light of the associated risks, although discussion continued regarding the prospect of presenting Mayer's biostatistics testimony. Having already flown in, Zibrak remained available to be called to offer pulmonology expert testimony. The downsides to placing a pulmonologist on the stand described above, coupled with the ground gained during the prosecution's case, convinced the Topel team his testimony involved more potential to damage their position than to enhance it.

The decision not to call Mayer is the cornerstone of Harkonen's present claims. According to Topel, the night before Mayer was to testify, the witness for the first time expressed doubt as to whether the press release was misleading. In the trial team's judgment, Mayer's testimony could no longer benefit Harkonen's case in light of this shift. While Hannon was still available as an expert biostatistician, he was significantly less credentialed than both Mayer and Fleming, and

thus, in defense counsels' opinion, risked undermining advances they had made during the prosecution's case. Together with Harkonen and his personal counsel Winchell, the trial team decided against calling any defense expert witnesses. In his closing argument, Topel highlighted the favorable points elicited during cross examination of government witnesses and explained to the jury, "our experts came through in the government's case . . . ." Trial Transcript at 3672-73. The six-week trial then came to a close.

On September 29, 2009, the jury reached a verdict finding Harknonen guilty on the wire fraud charge and acquitting him on the felony misbranding charge. The defense then filed a motion for judgment of acquittal contending in part that the government had failed to qualify its biostatisticians as experts, and thus rendered it impossible for the jury to conclude that the press release was misleading. In denying the motion, the trial court noted that although the government did not officially proffer either Fleming or Crager as experts, both were listed in its expert witness disclosure, and Fleming's curriculum vitae had been entered into evidence. Harkonen could, moreover, have attempted during cross-examination to undermine the jury's confidence in their credentials or testimony, but instead chose to focus on questions about statistical methodology. "Most damningly," in the words of the trial judge, Harkonen had raised no objections to Crager or Fleming's opinions about fundamental principles of biostatistical analysis or to their interpretation of secondary endpoint and post-hoc subgroup analyses. Dkt. No. 369. Because this testimony went unchallenged, reasoned the trial court, it was properly introduced and appropriate for the jury to have relied upon it in reaching its verdict.

Harkonen engaged a new defense team led by attorney Mark Haddad in December 2009 prior to the sentencing proceedings. Haddad's team presented declarations from Zibrak. It also presented declarations from Drs. Steven Goodman and Donald Rubin, biostatisticians new to Harkonen's case. Zibrak's declaration spoke to the biological plausibility of Actimmune's survival benefits and the lack of relevance of the press release to doctors' prescribing habits. His supplemental declaration stated that GIPF-001 did not "conclusively prove[] the efficacy of Actimmune for IPF," that he had stopped prescribing Actimmune to his IPF patients, and that

insurance companies are loath to reimburse for it. Dkt. Nos. 284, 317. Goodman's declarations countered government testimony relied on by the jury concerning biostatistical analysis. Specifically, he asserted, a p-value of 0.05 is not necessarily a "magic" threshold for statistical significance, and that reasonable scientists apply a lower standard of proof of efficacy when dealing with fatal diseases like IPF, for which there exist no known effective treatments. Dkt. Nos. 282, 318. Rubin, in similar fashion, stated that the GIPF-001 results did not foreclose the conclusion that Actimmune retained survival benefits. Dkt. No. 283. Haddad's sentencing presentation also included the DVD excerpts Harkonen's prior counsel chose not to use, in which experts of various types shared positive impressions of the trial results.

The Haddad team also filed two motions for a new trial, which the trial court heard in conjunction with the sentencing hearing on April 13, 2011. The first was based on an alleged *Brady* violation, arising from the late disclosure of documents from the Department of Veterans' Affairs supporting the press release's lack of materiality to prescribing decisions. In denying this motion, the trial court noted that Harkonen had elected not to pursue ample opportunities at trial to mount an immateriality defense, including his option to present experts on the point, and so had waived his right then to raise the materiality point via a *Brady* motion. The second new trial motion arose from purported new evidence in the form of an amicus brief filed by the United States in a different case, *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), in which the government arguably took a position on statistical methodology opposite to the one it took in Harkonen's case. The trial judge denied the motion, finding that a Supreme Court decision issued a year after the jury verdict was reached could not constitute "newly discovered evidence" in this instance under Rule 33 of the Federal Rules of Civil Procedure.

While the trial judge had before her all of the evidence accumulated by the Haddad team that had not been presented at trial, she nevertheless proceeded with sentencing based on the jury's verdict. The sentencing decision rejected the government's proposed ten-year prison sentence in favor of three years of probation and a $20,000 fine, largely on grounds of the press release's materiality. It found that while the press release had "undoubtedly" influenced some individuals

to recommend or seek treatment with Actimmune, the government's materiality case was exceptionally weak in that it had failed to attribute to the press release any specific instances in which Actimmune had been prescribed. Thus, for the purpose of considering sentence enhancement, the trial court found no actual or intended losses stemming from the conduct for which Harkonen had been convicted. *See* Sentencing Hearing Transcript at 77-78, 117.

Harkonen appealed his conviction on April 25, 2011, and the government cross-appealed the sentencing decision on May 12, 2011. Harkonen emphasizes that, in affirming the trial court's decision, the Ninth Circuit's March 2013 unpublished opinion noted that Harkonen had for the first time presented his strongest evidence at sentencing, and "[b]ecause we must defer to the jury's credibility determinations, we will not reverse the jury's verdict based on evidence it never considered." *United States v. Harkonen*, 510 Fed. Appx. 633, 637 n.2 (9th Cir. 2013).

On August 23, 2011, Harkonen filed a professional negligence action in state court against Topel and the Kasowitz firm arising from the representation he received in his criminal case. On May 7, 2013, the Ninth Circuit denied his petition for rehearing en banc; and the Supreme Court denied his petition for writ of certiorari on December 16, 2013. His three-year probation term concluded on April 13, 2014.

The Topel team's mistakes, Harkonen contends, precluded him not only from the benefit of exculpatory evidence at trial, but also from consideration of such evidence on his motion for acquittal and before the Ninth Circuit. On grounds of ineffective assistance of counsel, Harkonen filed this petition on July 30, 2014.

III. LEGAL STANDARD

"[T]he writ of error coram nobis is a highly unusual remedy, available only to correct grave injustices in a narrow range of cases where no more conventional remedy is applicable." *United States v. Riedl*, 496 F.3d 1003, 1005 (9th Cir. 2007); *see also United States v. Morgan*, 346 U.S. 502, 511 (1954) (characterizing the writ as an "extraordinary remedy" available "only under circumstances compelling such action to achieve justice"). It bridges the "very precise gap" in federal criminal procedure for post-conviction defendants for whom relief to have a sentence or

conviction vacated, set aside or corrected under the federal habeas corpus provision, 28 U.S.C. § 2255, is unavailable because they have already completed their time in federal custody. While Fed. R. Civ. P. 60(b) abolished this remedy in civil cases, the Supreme Court has thus maintained its availability in the criminal context. *Telink, Inc. v. United States*, 24 F.3d 42, 45 (9th Cir. 1994).

To obtain relief under the writ, a petitioner carries the burden to demonstrate that (1) a more usual remedy is unavailable; (2) valid reasons kept the petitioner from attacking his or her conviction earlier; (3) the conviction bears consequences sufficiently adverse to satisfy Article III's case or controversy requirement; and (4) the error is of the "most fundamental character." *Hirabayashi v. United States*, 828 F.2d 591, 604 (9th Cir. 1987). Conceding the first and third factors, the government contends only that Harkonen fails to show both valid reasons for not attacking his conviction at an earlier point, and that any error was of a fundamental nature.

IV. DISCUSSION

A. Timeliness of Harkonen's Attack

Although the writ of error coram nobis is not subject to any particular statute of limitations, the petitioner bears the burden of proof to offer valid reasons for delay. *Hirabayashi*, 828 F.2d at 604; *Morgan*, 346 U.S. at 12 (requiring a showing that "sound reasons exist for failure to seek appropriate earlier relief"); *Kwan*, 407 F.3d at 1014 ("The law does not require [petitioner] to challenge his conviction at the earliest opportunity, it only requires [petitioner] to have sound reasons for not doing so.").

Harkonen filed this petition on July 30, 2014: three months after completing his probation, seven months after the Supreme Court denied his petition for cert, over a year after the Ninth Circuit's affirmance of his conviction, and nearly three years after filing his state court professional negligence suit. Final judgment in hand in December 2013, Harkonen could technically have mounted a collateral attack on his conviction under Section 2255 between that time and the conclusion of his probation in April 2014. He contends, however, that financial constraints occasioned by his parallel Medical Board proceedings and clawback arbitration brought by InterMune for his trial defense cost; the effort required to retain present counsel to

prepare this petition; the time required properly to investigate evidence concerning Harkonen's representation at trial; and the long duration of his appellate proceedings from April 2011 to December 2013, all kept him from filing such a collateral attack during his probation period.

Even accepting these reasons as valid causes for Harkonen's inability to file a habeas petition, Harkonen nevertheless fails to address fully in his motion or reply why he declined to raise a direct challenge to his conviction on grounds of ineffective assistance prior to sentencing, via a motion for a new trial or in support of arguments for a downward departure. He does not contest that all evidence supporting his claim was available to him, and that he could have retained counsel separate from Topel and Haddad's teams to represent him on such a claim. Indeed, his state court professional negligence action was filed in August 2011 while Haddad continued to represent Harkonen on appeal.

Rule 33 requires a defendant's motion for a new trial for any reason "in the interest of justice" other than newly discovered evidence to be raised within fourteen days of the guilty verdict. *See United States v. Allen*, 153 F.3d 1037, 1045 (9th Cir. 1998) (affirming trial court's denial of Rule 33 motion for new trial based on "newly discovered evidence" of ineffective assistance of counsel) (internal citations and quotation marks omitted). Harkonen points out that such a motion grounded on allegations of ineffective assistance had to have been filed under Rule 33 within fourteen days, and that this window had expired by the time the Topel team's initial new trial motion citing newly discovered evidence had been denied. His reply moreover invokes case law suggesting that collateral attack is the customary approach for raising ineffective assistance claims, and that courts are "chary" of analyzing such claims on direct motion or appeal, given that a fuller record may be developed in a Section 2255 proceeding. *See United States v. Schaflander*, 743 F2d 714, 717 (9th Cir. 1984); *United States v. McGowan*, 668 F.3d 601, 606 (9th Cir. 2012).

Such a motion was, however, procedurally permissible, and Harkonen offers no insight as to what precluded such a filing. *See McGowan*, 668 F.3d at 606 (dismissing ineffective assistance claim without prejudice to its renewal in a Section 2255 petition). Harkonen also ignores the express permission in Federal Rule of Criminal Procedure 45 to extend a party's time period to act

"after the time expires if the party failed to act because of excusable neglect." This provision has supported a finding that a defendant's ineffective assistance claim made seven months after conviction was not untimely. *See United States v. Brown*, 623 F.3d 104, 112 (2d Cir. 2010). Why Harkonen did not immediately pursue a new trial on ineffective assistance grounds, or attempt to show excusable neglect under Rule 45 in order to make such a motion after fourteen days had expired. Especially in light of his ample access to legal counsel before, throughout, and after trial, and other extensive efforts to challenge his conviction, his failure to do so remains unexplained.

Harkonen's window to raise ineffective assistance claims in support of a downward sentencing departure was, moreover, far broader. Convicted in September 2009, he had until his April 2011 sentencing to offer evidence of his counsel's purported incompetence to the trial court. *See Rivera-Sanchez*, 222 F.3d 1057, 1060 (9th Cir. 2000) (permitting a direct appeal of ineffective assistance claim where the district court had held a hearing to examine the question for purposes of determining whether it warranted a downward sentencing departure). Given that Harkonen engaged Haddad's team to replace Topel well in advance of sentencing, and Haddad filed for sentencing purposes several pieces of evidence the Topel team had declined to use at trial, it is unclear why Haddad did not also pursue Harkonen's present allegations against Topel and his associates further to strengthen the case for a reduced sentence.

Delay has been ruled reasonable in this circuit where the applicable law changed, previously unavailable evidence was uncovered, or where counsel improperly advised the petitioner to forego seeking habeas relief. *See Reidl*, 496 F.3d 1003, 1007 (9th Cir. 2007) (aggregating cases). In *Reidl*, the petitioner's coram nobis action failed on timeliness despite the petitioner's attempt to justify her delay with arguments not dissimilar to those Harkonen presents here. Convicted in November 1999 and sentenced to 66 months in prison and subsequent deportation pursuant to the conviction, Reidl raised her coram nobis action in January 2006, about a year after completing her sentence and being deported to Austria. Reidl cited her incarceration, diminished capacity, forfeiture of certain assets, and her deportation to justify the timing of her petition. The Ninth Circuit noted, however, that none of Reidl's reasons explained why she didn't

raise her challenges—void-for-vagueness and insufficient evidence arguments—during trial, on direct appeal, or through a habeas petition. It, indeed, found "fatal" her concession that she could "have possibly" raised the claims on direct appeal or under Section 2255. *Id.* at 1006.

Like Reidl, Harkonen has not identified a case showing he was foreclosed from any possible opportunity to raise his ineffective assistance claim at an earlier juncture. *See Maghe v. United States*, 710 F.2d 503, 503-04 (9th Cir.1983) (denying coram nobis petition as untimely where claim could have been raised earlier and there were no sound reasons for the delay). Prior to sentencing, and arguably throughout all of his proceedings, Harkonen appears to have had ample access to assets and counsel, and consistently demonstrated that he was willing and able to apply these resources to challenging his conviction. Nor does he contend that incompetent counsel hampered him from raising his claims. As noted earlier, he pursued a professional negligence suit against the Topel team in state court soon after his sentencing.

In addition, Harkonen's attempt to raise the equitable doctrine of laches in order to advocate for application of an analogous statute of limitations to his coram nobis action is misplaced. Laches is an equitable defense a respondent may raise; in doing so, the respondent undertakes the burden to make a prima facie showing of prejudice due to the petitioner's delay. In such contexts, courts may look to analogous statutes of limitations to determine whether laches should apply. If the respondent meets his or her initial burden to show prejudice, it is then up to the petitioner to demonstrate that the respondent was not actually harmed by the delay, or that the petitioner applied reasonable diligence in filing his or her claim. *United States v. Reidl*, 496 F.3d 1003, 1008 (9th Cir. 2007); *Telink*, 24 F.3d at 47. Here, the government has not raised any laches argument as a supplemental defense that would then make the statute of limitations for a provision analogous to the writ an appropriate factor to consider. Rather, the key question is the one posed under *Hirabayashi*'s second prong (valid reasons for not attacking conviction earlier), and the one Harkonen has failed to answer. His petition thus appears deficient under this prong. In any event, as addressed below, it is most certainly deficient under *Hirabayashi*'s fourth prong (is the error of the "most fundamental" character?).

B. Nature of the Error: Ineffective Assistance of Counsel

The Ninth Circuit has recognized ineffective assistance of counsel under *Strickland v. Washington* as constituting fundamental error sufficient to sustain a coram nobis petition. *See United States v. Chan*, 2015 WL 4113883 (9th Cir. July 9, 2015); *United States v. Mett*, 65 F.3d 1531, 1534 (9th Cir. 1995) (holding that a post-conviction defendant no longer in custody may petition under the writ of error coram nobis to attack his conviction on Sixth Amendment assistance of counsel grounds). According to *Strickland*'s two-part test, a petitioner received ineffective assistance where counsel's performance fell below "objective standards of reasonableness" and, if it did, "there is a reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different." 466 U.S. 668 at 694.

Courts exercise considerable deference when reviewing the reasonableness of trial counsel's conduct in order to avoid the "distorting effects of hindsight." *Smith v. Stewart*, 140 F.3d 1263, 1268 (9th Cir. 1998) (internal citations and quotation marks omitted). According to Harkonen, the Topel team's failure to call defense expert witnesses was, nevertheless, objectively unreasonable.

The team first erred, he contends, when it decided against putting any biostatistician on the stand to counter the government experts' interpretation of the GIPF-001 trial's reported p-values and endpoints. That they didn't have another qualified biostatistician in the wings when Mayer appeared to equivocate, he argues, reflects incompetence. Yet the government documents extensively the Topel team's thorough investigation of Harkonen's case; their search far and wide for well-credentialed experts willing to testify in Harkonen's favor and against the government's likely expert witnesses; and the effort they expended confirming the positions of these witnesses, assessing their demeanor and articulateness, and preparing them for trial. While courts have found counsel's performance deficient in instances where it is clear that counsel failed to explore reasonable defenses, *see Luna v. Cambra*, 306 F.3d 954, 961 (9th Cir. 2002) (counsel's inadequate performance not challenged on appeal where counsel failed to interview and subpoena two alibi

witnesses and an exonerating witness), strategic decisions made subsequent to a rigorous investigation of relevant law and facts are "virtually unchallengeable." *Strickland*, 466 U.S. at 690.

Here, after having prepared as many experts as reasonably possible, the Topel team evaluated headway made through cross examination of prosecution witnesses and weighed perceived risks of relying on these gains versus calling their own witnesses. The decision of whether to place a prepared witness on the stand is one that draws "heavily on professional judgment," and courts "are not in a position to second-guess." *Lord v. Wood*, 184 F.3d 1083, 1095 n.8 (9th Cir. 1999).

Harkonen, citing a supplementary declaration from Mayer, contends the expert did not at any point express to Topel thoughts that the press release might be misleading. Mayer does indeed declare that he maintains "no specific memory of doing so," and moreover that "if I did it was in the context of explaining that an FDA regulator or a trialist such as Fleming might think the release misleading." Dkt. No. 423, Ex. L. Yet whether or not Mayer expressed clear doubts to Topel about his position the night before he was to testify, Topel and Harkonen's several other attorneys—many of whom had spent considerable time evaluating Mayer's strengths as a witness and preparing him to testify—considered Mayer's demeanor and behavior, and made a calculated strategic decision against calling him to the stand. Harkonen's contentions that Topel failed to spend adequate time preparing Mayer and rushed through the trial for personal reasons are unsupported, if not contradicted, by the record.

Even assuming that Mayer never faltered from his original stance on the press release, his behavior coupled with the concessions already elicited from government experts gave the Topel team reason to believe they had more to lose than gain from Mayer's live testimony, and thus needed to shift course. The reasons the government furnishes for the Topel team's decision against pitting Hannon against the more highly-accredited and influential scientist Fleming are, likewise, objectively reasonable.

Harkonen next asserts that his counsels' decision against calling Zibrak, their lead

pulmonology expert, to speak on the press release's materiality and his positive experiences prescribing Actimmune for IPF patients, similarly constituted performance falling below objective standards of reasonableness. It is not in dispute, however, that Zibrak's position in his expert disclosure was that doctors do not make prescribing decisions "solely" on the basis of a press release. Opp. p. 70. His testimony would therefore have tended to support the government's position that the press release was among factors capable of influencing prescribing decisions, and was thus material. Further, while Zibrak had used Actimmune to treat patients, by the time of trial, he had ceased prescribing it. The risk Topel's team perceived that Zibrak's testimony could open the door to evidence from GIPF-007 that would be catastrophic to Harkonen's use of the prior study in the press release, prompting their decision against placing him on the stand, was therefore not beyond the pale of reasonableness. Harkonen furthermore does not dispute that he and his independent counsel Winchell were involved in the team's final strategic decision not to call any defense witnesses.

Harkonen further argues in his reply that the Topel team's decisions were also objectively unreasonable in that they failed to line up Goodman and Rubin, whose declarations were introduced at sentencing by the Haddad team, as experts at trial. As noted, both scientists' declarations suggested that reasonable researchers sometimes apply lower standards for proof of efficacy in certain instances like the one here, in which the drug being tested is for a fatal disease with no known effective treatments; and that the GIPF-001 study's results did not entirely foreclose a conclusion that Actimmune showed survival benefits. Harkonen's contention on this score fails for two reasons. First, there is no indication that the testimony of either Goodman or Rubin would have altered the trial's result (indeed, the trial judge forged ahead with sentencing even after assessing their declarations). Second, Harkonen himself acknowledged that the opinions of both those experts constituted "newly discovered evidence" not previously available despite counsels' exercise of reasonable diligence in their search for experts. *See* Dkt. No. 293.

Harkonen finally contends that his trial counsel committed fundamental error when they failed to introduce the DVD excerpts at trial to counter the government's assertion that GIPF-001

represented a complete failure. Again, however, this decision appears to have been reached through an objectively reasonable consideration of a multitude of factors. Upon several reviews of the tapes, Harkonen's attorneys concluded that even where physicians shared positive impressions of Actimmune's potential to yield survival benefits to IPF patients, they did not affirm GIPF-001's statistical significance, and, by contrast, shared reasons why the results as reported in the press release were "controversial" and would be subject to criticism. Opp. p. 78, 80. Their attempts to contact scientists on the tapes to serve as trial witnesses in Harkonen's favor were, in addition, fruitless, casting doubt on the reliability of the positions taken in the tapes, and raising hearsay inadmissibility issues the team would face if they attempted to introduce the DVD clips at trial in the absence of the taped experts.

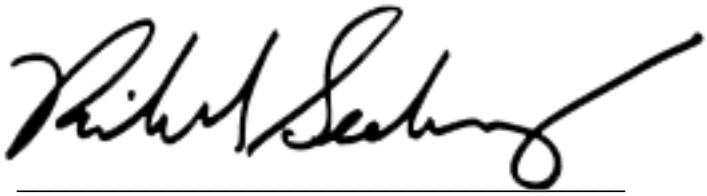
Because ample evidence supports a finding that each of these strategic decisions was objectively reasonable, *Strickland*'s second prong (the "but-for" test) need not even be reached here. An adequate showing of prejudice requires that the petitioner demonstrate counsel committed errors so serious that they undermine confidence in the verdict originally reached. *Strickland*, 466 U.S. at 693-94. Harkonen's case, at best, highlights close judgment calls made by his attorneys that perhaps in hindsight resulted in lost opportunities to present evidence that could have swayed the jury in his favor. That each of these decisions was made in response to legitimately perceived risks, however, precludes a finding that the verdict reached in Harkonen's case should be questioned.

V. CONCLUSION

In that Harkonen fails to identify valid reasons for declining to attack his conviction earlier, and falls short of demonstrating that he received ineffective assistance of counsel under *Strickland*'s rigorous standard, his petition for the writ of error coram nobis must be denied.

IT IS SO ORDERED.

Dated: August 21, 2015



RICHARD SEEBORG
United States District Judge

United States District Court
Northern District of California